


Memorandum

To: Intertek **Date:** 8/8/2014

From: Dan Brisco  **c.c.:**

Subject: Changes to FCC ID: YTESM03 since Permissive change dated 7/27/11


This memo is intended to summarize the changes made to FCC ID: YTESM03 since Permissive change dated 7/27/11. The most notable changes are to the antenna and the artwork for the enclosure. There have been some changes to the BTE; however none of them affect the radio.

- Radio section Documents that have changed: Antenna specification

Non-Radio section Documents that have changed:

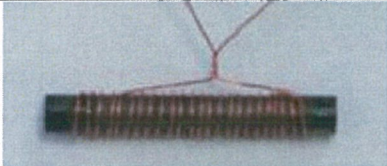
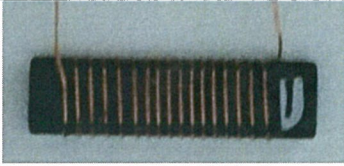


- User manual
- Internal Photos and Drawing
- FCC/IC artwork
- Parts List
- Block Diagram
- Schematic

BTE

	<u>SoundBite (2011)</u>	<u>SoundBite G3 (2014)</u>
Mechanical design		No Change
Material: - Housing, enclosure	Polyetherimide GE Plastics (Sabic) ULTEM HU 1010 According to the material certification from the supplier the material pass the requirements outlined by ISO10993 for cytotoxicity, irritation and sensitization USP class VI Certified	No Change

	<u>SoundBite (2011)</u>	<u>SoundBite G3 (2014)</u>
Material: - Housing, connector / stress relief	GE Plastics (Sabic) Lexan HP 1 According to the material certification from the supplier the material pass the requirements outlined by ISO10993 for cytotoxicity, irritation and sensitization USP class VI Certified	Evonik Industries, TROGAMID Care MX73 The microphone assembly has been tested by Sonitus Medical for Cytotoxicity, Sensitization and irritation and meets the applicable ISO10993 requirements for biocompatibility.
Material: - Microphone Tubing	Pebax 7233 Cleared as patient contacting material for cardiovascular catheters (e.g. K042553, K052004, K080988) USP class VI Certified	No Change
Material: - Housing, microphone	Polietherimide GE Plastics (Sabic) ULTEM HU 1010 According to the material certification from the supplier the material pass the requirements outlined by ISO10993 for cytotoxicity, irritation and sensitization USP class VI Certified	GE Plastics (Sabic) Cyclopy HC1204HF The microphone assembly has been tested by Sonitus Medical for Cytotoxicity, Sensitization and irritation and meets the applicable ISO10993 requirements for biocompatibility.
Material: - Electrical contacts	Gold plated pin Cleared for breached skin surface (K091055, K091721, K032951)	No Change
Material: - Ear dome/plug	Silicone LSR (liquid silicone rubber) Cleared for urology (K915571, K970855, K045182, K080007)	No Change
Material: - Adhesive	Loctite M-121 HP Epoxy Adhesive USP class VI certified	No Change

	<u>SoundBite (2011)</u>	<u>SoundBite G3 (2014)</u>
Electrical Design	 Rev A	Rev B = Fixed Typos. Add Assembly notes Rev C =Add D4, 5, 7 (ESD protection) Rev D =DSP Firmware change (No Radio Firmware change). Rev E =4.1VDC Battery Charge IC Rev F =Changed R20 from 1.0M to 619K (more reliable patient fitting) Rev G =DSP Firmware Change (No Radio Firmware change). 
Electronic Design: - Flammability grade	UL-94 V0	No Change
Electrical design: - Radio	On-Semi SA3410 hybrid including NXP NxH2180 radio. Operating frequency: 10.6MHz Modulation scheme: CPFSK	No Change
Electrical design: - Battery operated	Internally powered: 2x Single cell Lithium-ion Polymer: Lishen PP031012AB Capacity: 2x 19mAh	No Change
Electrical design: - Battery short / over current circuit protection	Seiko Instruments S-8211CAZ-I6T1G	No Change
Electrical design: - Battery charger	Linear Technology LTC4065L	LTC4065L-4.1 (battery longevity increase)
Electrical design: - Voltages	4.225V maximum voltage	4.142V maximum voltage

	<u>SoundBite (2011)</u>	<u>SoundBite G3 (2014)</u>
Electronic design: - Charge terminal leakage	1.25V, 8uA	No Change
Antennas		
Antennas: - Dimensions	Rod: L15mm x D2mm	Rod: L15mm x H2mm x W4mm
Antennas: - Inductance	3.8uH	No Change
Antennas: - Core material	FairRite material 61	No Change
Labeling	Laser Etch	No Change
BTE label content		 Add IC: ID